AGH Polyastomer		3	Trademark Appl. drwg, $	4-11-95	AGH
AGH Malanchuk	(EPA)	1	Appl. drwg., dec, IDS, $	4-11-95	"
AGH Hamagucchi 1	(Niiz)	08/111,510	IFF	4-11-95	"
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AGH Hentze 1	(Hane)	08/035,073	Amnd, drwgs	4-11-95	"
Grp Lynapel 2A	(Colb)	08/111,014	Pmn w/ clm #	4-11-95	AGH
Grp Gibbons 2	(VIDD)	07/852,206	PTR, decl, term disclm, exh	4-11-95	"
Grp Gielen 1	(POLA)	1	App, dec, Bas #, 1449	4-12-95	AGH
AGH Mertens	(Have)	4	App, drwgs	4-12-95	"
Grp Langevecker	(Biom)	5 PCT	App, drgs (14), Bas #	4-12-95	"
Grp Komitka 1	(Tomi)	08/190,447	Sub of References	4-12-95	"
Grp Meyhuysen 4	(Plou)	07/689,077	AF Amn w/ext	4-12-95	"
Grp Classen 1	(Clas)	08/104,529	Notice of Appeal	4-12-95	"
Grp Classen 1	(Clas)	08/104,529	SMN AF Amn	4-12-95	"
Grp Klaus 1	(Grun)	08/050,184	Amendment w/ext	4-12-95	"
Grp Awasaki 11	(Argb)	08/148,917	IDS w/refs	4-12-95	"
Grp Miller 8A		08/284,298	Amendment w/2 exts	4-12-95	"
Grp Heads up 1		74/519,169	Communication	4-12-95	"
Grp Saah 8	(Kirb)	08/271,447	Amendment w/ext	4-12-95	AGH
Lm Saika 1	(Take)	4,699,244	2nd MF	4-13-95	AGH
Lm Guilard 1A	(LAIR)	07/945,575	IFF	4-13-95	AGH
Lm Tanaka 22	(ASAM)	5,056,937	1st MF	4-13-95	AGH
Lm Goring 1	(Made)	5,057,256	1st MF	4-13-95	AGH
Lm Bouillonc 1	(Rhon)	5,056,549	1st MF	4-13-95	AGH
Lm IIDA 6	(Yuao)	5,057,317	1st MF	4-13-95	AGH
Lm Fujioshi 1	(ONAK)	5,052,245	1st MF w/surcharge	4-13-95	AGH
AGH Chen 146	(Lien)	29/024,155	Response	4-13-95	AGH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1805
CLASSEN, J.B.	)	Examiner: VOGEL, N.
Serial No.: 08/104,529	)	Washington, D.C.
Filed: August 12, 1993	)	April 12, 1995
For: METHOD AND COMPOSITION FOR AN...	)	Atty's Docket: CLASSEN=1

NOTICE OF APPEAL FROM THE PRIMARY EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the final rejection (or the rejection of claims for at least the second time), dated October 12, 1994 of the Primary Examiner. The claims appealed are 2-18, 21-35 and 37.

The item(s) checked below are appropriate:

XX Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.

___ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

XX The fee has been calculated as shown below:

___ $280.00
XX $140.00 (small entity)
___ Not required (fee paid in prior appeal)

A three month-extension of time was petitioned and paid for on April 10, 1995.

XX A check in the amount of $140.00 is attached. (Check No. 8880)

XX Please charge any deficit in the fee paid herewith to my Deposit Account No. 02-4035.

Respectfully submitted,
BROWDY AND NEIMARK
Attorneys for Applicant(s)

By _____
Iver P. Cooper, Esq.
Reg. No. 28,005

Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms

BROWDY AND NEIMARK
419 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004

NOT VALID FOR MORE THAN $5,000 OR IF PAYABLE TO ANY PARTY OTHER THAN THE HON. COMMISSIONER OF PATENTS AND TRADEMARKS

008880

15-3
540
44

March 11 19 95

PAY TO THE ORDER OF HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS $ 140.00

One hundred forty and 00/100 DOLLARS

The Riggs National Bank
Market Square Office
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DOCKET # CLASSIC-1

PTO ID. # 08/104,529

NON-NEGOTIABLE

[redacted]

APPLICANT(S) CLASSEN, J.B. (Clas) DKT. NO. CLASSEN=1

SERIAL NO. 08/104,529 FILED August 12, 1993

PTO stamp was faint — see darker copy

THE PATENT AND TRADEMARK OFFICE STAMP HEREON ACKNOWLEDGES RECEIPT OF THE FOLLOWING PAPERS:

- ☒ FEES $ 170.00 (CH. # 2666)
- ☐ MISSING PARTS RESPONSE W/DECL.
- ☐ INVITATION TO CORRECT DEFECTS
- ☐ AMENDMENT
- ☐ RESPONSE
- ☒ NOTICE OF APPEAL
- ☐ APPEAL BRIEF (TRIPLICATE)
- ☐ ASSIGNMENT
- ☐ EXTENSION OF TIME (_____ MONTHS)
- ☐ PRIORITY DOCUMENT(S)
- ☐ LETTER TO DRAFTSMAN
- ☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27
- ☐ OTHER

- ☐ DEMAND FOR CHPT. II
- ☐ ISSUE FEE TRANSMITTAL FORM
- ☐ DECLARATION UNDER § _____
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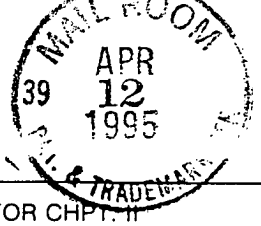
- ☐ _____ SHEETS OF DRAWINGS
- ☐ TRANSMITTAL LETTER
- ☐ MAINTENANCE FEE LETTER

B&N-1

APPLICANT(S) CLASSEN, J.B. (Clas) DKT. NO. CLASSEN=1

SERIAL NO. 08/104,529 FILED August 10, 1993

THE PATENT AND TRADEMARK OFFICE STAMP HEREON ACKNOWLEDGES RECEIPT OF THE FOLLOWING PAPERS:



- ☐ FEES $ _____ (CH. # _____)
- ☐ MISSING PARTS RESPONSE W/DECL.
- ☐ INVITATION TO CORRECT DEFECTS
- ☒ AMENDMENT Supplemental AFTER FINAL
- ☐ RESPONSE
- ☐ NOTICE OF APPEAL
- ☐ APPEAL BRIEF (TRIPLICATE)
- ☐ ASSIGNMENT
- ☐ EXTENSION OF TIME (_____ MONTHS)
- ☐ PRIORITY DOCUMENT(S)
- ☐ LETTER TO DRAFTSMAN
- ☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27
- ☐ OTHER

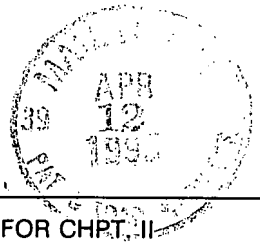
- ☐ DEMAND FOR CHPT. II
- ☐ ISSUE FEE TRANSMITTAL FORM
- ☐ DECLARATION UNDER § _____
- ☐ INFORMATION DISCLOSURE STATEMENT
- ☐ _____ SHEETS OF DRAWINGS
- ☐ TRANSMITTAL LETTER
- ☐ MAINTENANCE FEE LETTER

B&N-1

APPLICANT(S) CLASSEN, J.B. (Class) DKT. NO. CLASSEN=1

SERIAL NO. 08/104,529 FILED August 12, 1993

THE PATENT AND TRADEMARK OFFICE STAMP HEREON ACKNOWLEDGES RECEIPT OF THE FOLLOWING PAPERS:



- ☒ FEES $ 140.00 (CH. # 8880)
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- ☐ INVITATION TO CORRECT DEFECTS
- ☐ AMENDMENT
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- ☒ NOTICE OF APPEAL
- ☐ APPEAL BRIEF (TRIPLICATE)
- ☐ ASSIGNMENT
- ☐ EXTENSION OF TIME (_____ MONTHS)
- ☐ PRIORITY DOCUMENT(S)
- ☐ LETTER TO DRAFTSMAN
- ☐ DEMAND FOR CHPT. II
- ☐ ISSUE FEE TRANSMITTAL FORM
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- ☐ INFORMATION DISCLOSURE STATEMENT
- ☐ _____ SHEETS OF DRAWINGS
- ☐ TRANSMITTAL LETTER
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- ☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27
- ☐ OTHER _____

B&N-1

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	ATTN.:	NANCY VOGEL
In re Application of:	)	Art Unit: 1805
CLASSEN, J.B.	)	Examiner: VOGEL, N.
Serial No.: 08/104,529	)	Washington, D.C.
Filed: August 12, 1993	)	April 12, 1995
For: METHOD AND COMPOSITION FOR AN...	)	Docket No.: CLASSEN=1

SUPPLEMENTAL AMENDMENT AFTER FINAL REJECTION

COURTESY COPY VIA FACSIMILE - (703-308-4312)
Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

IN THE CLAIMS

Cancel claim 15.

In claim 37, line 19, as amended on April 10, 1995, replace "before" with --after--.

Please amend claims 22 and 28 as follows:

22 (amended). The method of claim 21 wherein said further administration

(a) comprises further administering to said mammal of at least 28 days of age but less than 175 days of age, at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen,

wherein said at least one dose comprises a total of at least 4 separate pharmaceutically acceptable doses of at least one pharmaceutically acceptable immunogen from the group consisting of a diphtheria/tetanus/pertussis immunogen, a hepatitis B immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen, a polio immunogen, and a non-

pediatric immunogen, administered to said mammal during said ages, at least 2 of said at least 4 doses provided prior to the age of 112 days of said mammal, and wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

28 (amended). In a method for pediatric immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age,

the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable supraimmunogenic dose of at least one pharmaceutically acceptable vaccine prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

REMARKS

The Examiner is thanked for reviewing the AMENDMENT AFTER FINAL REJECTION filed April 10, 1995, and for bringing to Counsel's attention the imperfections addressed here. The Examiner indicated that the Amendment, with these additional corrections, appeared to fully address all rejections, but that she would have to review the case with her superior to determine

if it were in condition for allowance.

Since the end of the statutory period has been reached, a notice of appeal is being filed on even date herewith to keep the application pending.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant

By:_____
Iver P. Cooper
Reg. No. 28,005

419 Seventh Street, N.W.
Washington, D.C. 20004
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms

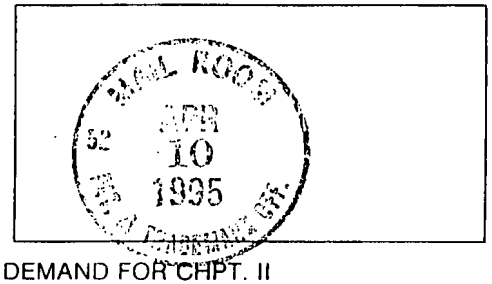
COPY

AGH ✓Hong 6	(Dire)	5,054,534	1st M-Fee	4-7-95	RER
AGH ✓Tran 1.1	(Infs)	5,055,120	1st M-Fee	4-7-95	RER
AGH ✓Margottau 1	(Made)	5,054,634	1st M-Fee	4-7-95	RER
AGH ✓Morel 7	(Made)	5,054,946	1st M-Fee	4-7-95	RER
AGH ✓Mattiolo 1		5,054,953	1st M-Fee	4-7-95	RER
AGH ✓Amirav 2	(Wolf)	5,055,677	1st M-Fee	4-7-95	RER
AGH ✓Nishimoto 1.1	(Tsuk)	5,055,575	1st M-Fee	4-7-95	RER
AGH ✓Kawamura 15	(Onak)	5,054,443	1st M-Fee	4-7-95	RER
AGH ✓Sakai 1	(Saku)	07/501,900	IFF	4-7-95	RER
AGH ✓Polsky 2	(Pols)	08/257,107	IFF	4-7-95	RER
AGH ✓Byrne 1	(Dnx)	07/948,521	Expedited cpy of asg.	4-7-95	RER
AGH ✓Sakai 4	(Saku)	07/501,900	Drwgs.	4-7-95	RER
AGH ✓Polsky 2	(Pols)	08/257,107	Drwgs.	4-7-95	RER
~~Sep~~ ✓Horikawa 1A	(Tsuk)	08/393,395	Notice of Incomplete Applu	4-7-95	RER
~~Sep~~ ✓Maue 2	(Cin-)	5,054,719	2nd M-Fee	4-7-95	RER
AGH ✓Mohss	(BIER)	1	Appln, prelim, suppl., dis., SES dec, drwgs $	4-10-95	AGH
AGH ✓Yakota	(Yuas)	2	Appln, dec (Nat'l Stage)	4-10-95	AGH
AGH ✓Jeppesen 1	(INTE)	29/032,130	Resp. to Request for Info, Prior Doc	4-10-95	AGH
AGH ✓Lindgren 3	(Awap)	29/012,609	Amend., Terminal Disclaimer, $	4-10-95	AGH
AGH ✓Lindgren 4	(Awap)	29/012,605	Amend., Terminal Disclaimer, $	4-10-95	AGH
AGH ✓Huang ~~63~~	(Dire)	63	Appl., SES, dec, drwgs. (4), $	4-10-95	AGH
AGH ✓Concetti 1		08/140,396	Comm. Re Notice of Allowability	4-10-95	AGH
AGH ✓Classen 1	(Clas)	08/104,529	Amnd., 3mth ext., $	4-10-95	AGH
AGH ✓Lagler 2	(Mage)	08/244,979	Comm. Re Small Entity Status	4-10-95	AGH
AGH ✓Zick 1 PCT	(Yeda)	PCT/US94/13679	2nd Chang of Name of Applicant	4-10-95	AGH
AGH ✓Gibboni 3 PCT	(Acts)	PCT/US95/02431	Req. for Ext. of Time	4-11-95	AGH
AGH ✓Chan	(P&T)	5	Des. Appl., drwgs., SES, dec, $	4-11-95	"
AGH ✓Masaki 65	(Saku)	08/301,816	Amnd	4-11-95	"
AGH ✓Tanaka 50A		08/337,140	Amnd	4-11-95	"
AGH ✓Paradis	(NYum)	1A PCT	PCT appl., drwgs., $	4-11-95	"
AGH ✓Bar-Shalom 1B	(Plow)	08/293,933	Amnd., 3 ext	4-11-95	"

APPLICANT(S) CLASSEN, J. B. ( ) DKT. NO. CLASSEN-1

SERIAL NO. 08/104,529 FILED August 12, 1993

THE PATENT AND TRADEMARK OFFICE STAMP HEREON ACKNOWLEDGES RECEIPT OF THE FOLLOWING PAPERS:



- [X] FEES $ 425.00 (CH. # 8972)
- [ ] MISSING PARTS RESPONSE W/DECL.
- [ ] INVITATION TO CORRECT DEFECTS
- [X] AMENDMENT
- [ ] RESPONSE
- [ ] NOTICE OF APPEAL
- [ ] APPEAL BRIEF (TRIPLICATE)
- [ ] ASSIGNMENT
- [X] EXTENSION OF TIME (3 MONTHS)
- [ ] PRIORITY DOCUMENT(S)
- [ ] LETTER TO DRAFTSMAN
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- [ ] ISSUE FEE TRANSMITTAL FORM
- [ ] DECLARATION UNDER § _____
- [ ] INFORMATION DISCLOSURE STATEMENT
- [ ] _____ SHEETS OF DRAWINGS
- [ ] TRANSMITTAL LETTER
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- [ ] VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27
- [ ] OTHER _____

B&N-1

BROWDY AND NEIMARK
419 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004

NOT VALID FOR MORE THAN $5,000 OR IF PAYABLE TO ANY PARTY OTHER THAN THE HON. COMMISSIONER OF PATENTS AND TRADEMARKS

008872

15-3
540 44

April 10 1995

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Four hundred thirty five and 00/100 DOLLARS

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Market Square Office
Washington, D.C. 20024-6758

DOCKET # CLASS IN=1

PTO ID. # 08/104,529

NON-NEGOTIABLE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: CLASSEN, J.B.
Serial No.: 08/104,529
Filed: August 12, 1993
For: METHOD AND COMPOSITION FOR AN...

Art Unit: 1805
Examiner: VOGEL, N.
Washington, D.C.
Atty.'s Docket: CLASSEN=1
Date: April 10, 1995

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP

Transmitted herewith is an [XX] Amendment [ ] _____ in the above-identified application.

[XX] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.

[ ] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

[ ] No additional fee is required.

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)	Small Entity			Other Than a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra		Rate	Additional Fee	Rate	Additional Fee
Total	33	Minus	37	=0		x11	$	x22	$
Indep.	11	Minus	15	=0		x22	$	x76	$
First Presentation of Multiple Dependent Claim						+120	$	+240	$
TOTAL ADDITIONAL CLAIMS FEE							$	Total	$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col.1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time
If any extension of time for a response is required applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity
Response Filed Within
[ ] First - $ 55.00
[ ] Second - $185.00
[XX] Third - $435.00
[ ] Fourth - $680.00
month after time period set

Other Than Small Entity
Response Filed Within
[ ] First - $ 110.00
[ ] Second - $ 370.00
[ ] Third - $ 870.00
[ ] Fourth - $1360.00
month after time period set.

[ ] Less fees ($) already paid for month(s) extension of time on .

[ ] Please charge my Deposit Account No. 02-4035 in the amount of $_____. A duplicate copy of this sheet is attached.

[XX] A check in the amount of $ 435.00 is attached (check no. 8872).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR Section 1.16 and all patent processing fees under 37 CFR Section 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR Section 1.18.

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By: _____
IVER P. COOPER
Registration No. 28,005

Facsimile: (202) 737-3528
Telephone: (202) 628-5197

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1805
CLASSEN , J.B.	)	Examiner: VOGEL, N.
Serial No.: 08/104,529	)	Washington, D.C.
Filed: August 12, 1993	)	April 10, 1995
For: METHOD AND COMP-OSITION FOR AN...	)	Docket No.: CLASSEN=1

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP _____

AMENDMENT AFTER FINAL REJECTION

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

IN THE CLAIMS

In claim 9, line 1, after "claim", insert --1--.

In claim 31, line 2, before "further administering", insert --(c)--.

In claim 32, line 2, before "administering", insert --(d)--, and at the end of the claim, add, --of step (c)--.

Please rewrite claims 3, 21, 23-27, 30, 33, 35 and 37 as follows:

3 (amended). [The method of claim 1] A method of immunizing a mammal less than 96 months of age against at least one infectious disease, while decreasing the incidence of diabetes mellitis, comprising

administering to said mammal one or more pharmaceutically acceptable pharmaceutical preparations, comprising one or more immunogens, according to an immunization schedule according to which, at specific times after birth, the mammal receives one or more pharmaceutically acceptable doses of one or more

immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence of diabetes mellitis in such mammals;

where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, for at least one such immunogen, either

(a) a plurality of doses of the immunogen are administered, and such doses are administered less than 28 days apart, or

(b) the immunogen is a live polio virus and at least five doses are given during the first 112 days after birth, or

(c) the immunogen is not a live polio virus, and at least four doses are given during the first 112 days after birth.

21 (amended). In a method for immunization against at least three infectious diseases, comprising administering at least one pharmaceutically acceptable dose of diphtheria/ tetanus/pertussis vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one

pharmaceutically acceptable dose of diphtheria/pertussis/ tetanus vaccine, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administrating at least two doses of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal;

(2) administering said at least one of said dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering at least a second dose of said diphtheria/tetanus/pertussis vaccine, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering said at least one dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering as a total of at least four doses of said diphtheria/tetanus/pertussis vaccine prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] <u>the</u> incidence [, prevalence, frequency, and severity of at least one chronic immune mediated disorder] <u>of diabetes mellitis</u> [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

23 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of

diphtheria/tetanus/pertussis vaccine and at least one pharmaceutically acceptable dose of hemophilus influenza vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one of a diphtheria/pertussis/tetanus vaccine and a hemophilus influenza vaccine wherein said further administration (a) is according to at least one method from the group consisting of

(1) administrating at least one dose of both said diphtheria/pertussis/tetanus vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and at least a second dose of at least one said vaccine prior to 42 days of age of said mammal;

(2) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and also administering at least a second dose of both of said vaccines, wherein said second dose and or any subsequent dose is administered at less than 42 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and administrating at least four doses, prior to the age of 112 days, of said mammal for said diphtheria/pertussis/tetanus vaccine or said hemophilus influenza vaccine, [wherein the further administration reduces [at least one measure

selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

24 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable first dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of a diphtheria/tetanus/pertussis immunogen, a polio immunogen, a hepatitis B immunogen, a hemophilus influenza immunogen, a non-pediatric immunogen, and a measles/mumps/rubella immunogen, to a mammal after 112 days of age but prior to 724 days of age, the improvement comprising

(a) further administering to said mammal, prior to the age of 112 days, at least one pharmaceutically acceptable second dose containing a greater amount of said immunogen than the amount of immunogen administered as said first dose after 112 days of age but prior to 724 days of age of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

25 (amended). In a method for immunization against at least two infectious diseases, comprising administering at

least one pharmaceutically acceptable dose of a non-whole cell pertussis vaccine to a mammal at least 42 days of age but prior to 724 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus immunogen, a non-whole cell pertussis immunogen, a whole cell pertussis immunogen, a polio immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen and a non-pediatric immunogen, wherein said further administration (a) is according to at least one selected from the group consisting of

(1) administrating said at least one dose of said immunogen at less than 42 days of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent said dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

26 (amended). In a method for immunization against at

least two infectious diseases, comprising administering at least one pediatric vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable vaccine selected from (i) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hemophilus influenza immunogens, and (ii) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hepatitis B immunogens,

wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administrating at least of one of said dose of said combined vaccine at less than 42 days of age of said mammal;

(2) administering at least one of said dose of said combined vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/ or subpopulation of said mammals.

27 (amended). In a method [of] for immunization against at least two infectious diseases and tolerizing against at least one antigen, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age and administering at least one tolerogen to said mammal,
the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus/pertussis immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen, a polio immunogen, and a non-pediatric immunogen, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administrating said at least one dose of said immunogen at less than 42 day of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,

wherein the further administration reduces <u>the</u> [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of

said disorder,] diabetes mellitis in a population and/ or subpopulation of said mammals.

30 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age,
the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal prior to the age of 8 days; and

(b) further administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal at least 11 days of age but less than 26 days of age,

wherein the further administrations reduce the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

33 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to a mammal,
the improvement comprising

(A) further administering at least a second pharmaceutically acceptable dose of at least one

pharmaceutically acceptable immunogen, said second dose and or any subsequent dose is administered less than 28 days after the preceding dose,

wherein said (i) second or any subsequent dose contains the same or different immunogens or the same or different amounts of said immunogens as any other dose; (ii) each said separate dose is administered during a 0-78 hour period, and (iii) the further administration reduces the [at least one measure selected from the group consisting of] incidence [, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and or subpopulation of said mammals.

35 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of hepatitis B vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of said hepatitis B vaccine according to at least one step selected from the group consisting of

(1) administrating at least 3 said doses of said vaccine at less than 56 days of age of said mammal;

(2) administrating said at least one dose of said vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than

175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,

wherein the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or of at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

37 (amended). A method of immunizing a mammal less than 96 months of age against at least two infectious disease and at least one chronic immune-mediated disorder, comprising

administering to said mammal one or more pharmaceutically acceptable pharmaceutical preparations, comprising one or more immunogens, according to an immunization schedule according to which, at specific times after birth, the mammal receives one or more pharmaceutically acceptable doses of one or more immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence [or severity] of [at least one chronic immune mediated disorder] diabetes mellitis in such mammal;

the first dose of said immunization schedule including an immune modulator beginning 42 days before birth,

where said mammal is not immunized with an immunogen in such amounts and at such times as would substantially induce [said immune-mediated disorder] <u>diabetes mellitis</u>.

REMARKS

1. The only substantive rejection in this case is against claims 2-18, 21-35 and 37, for insufficient enablement. However, the Examiner concedes that the disclosure is enabling for "a method [of immunizing] mammals which decreases the incidence of diabetes mellitis". In the interest of speedy resolution, Applicants have amended claims 3, 21, 23-27, 30, 33, 35 and 37 so that all pending claims are limited to the admittedly enabled indication. This is without prejudice or disclaimer to pursuing the subject matter in a continuing application.

2. Certain of the claims were also rejected for indefiniteness.

2.1 Claim 3 has been rewritten in independent form, hence, claims 2-18 are no longer dependent on cancelled claim 1.

2.2 Claim 9 has been amended to refer to claim 3.

2.3 The Examiner states that she is uncertain of what was intended by claim 32. However, the quoted language is from original claim 31, not 32, and does not reflect the correction of "proceeding" to --preceding-- in the last amendment.

An example or an immunization schedule within claim 31 is the following:

Dose	Age	
1	7 days	[see claim 30 (a)]
2	14 days	[see claim 30 (b)]
3	21 days	[ditto]
4	42 days	[see claim 31 and preamble of claim 30]

Dose 1 is given prior to the age of 8 days, and doses 2 and 3 between the ages of 11 and 26 days. The last dose at an age preceding 26 days of age was dose 3 at 21 days of age. Dose 4 was administered 21 days later, which is within the claimed interval of "at least 11 days, but less than 26 days".

Claim 32 would cover an administration schedule in which to the above schedule one added a dose 5 at age 63 days. This would be 21 days (i.e., between 11 and 26 days) after the "further administration" recited in claim 30.

To clarify these claims, we have inserted an identifying --(c)--, before the "additionally administering" at the beginning of the second line of claim 31, and an identifying --(d)-- before "administering" at the beginning of the second line of claim 32. In addition, at the end of claim 32, after "administration", we have added --of step (c)--.

It is respectfully concluded that the claims are now in condition for allowance.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant

By: _____
Iver P. Cooper
Reg. No. 28,005

419 Seventh Street, N.W.
Washington, D.C. 20004
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms

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